

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

In re: Rosuvastatin Calcium Patent Litigation

)
) C.A. No. 08-md-1949-JJF
)
) **PUBLIC VERSION**
)

**DEFENDANTS' REPLY IN SUPPORT OF THEIR
MOTION TO EXCLUDE THE EXPERT TESTIMONY OF MAMI HINO**

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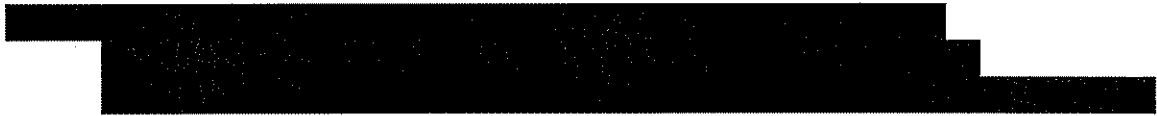
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Defendants Cobalt Pharmaceuticals, Inc., and Cobalt Laboratories, Inc., on behalf of all Defendants in the above coordinated actions (collectively, “Defendants”), respectfully submit this Reply in support of their Motion to Exclude the Expert Testimony of Mami Hino, offered by Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively, “Plaintiffs”).¹

I. INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiffs fail to cite a single case in which any court has allowed expert evidence to negate (or establish) intent to deceive the PTO. Nor have Plaintiffs cited a case to support the admissibility of an expert’s subjective interpretation and assessment of foreign-language documents as admissible evidence, summary or otherwise, of the documents’ contents.

Plaintiffs initially deny offering Ms. Hino’s expert opinions as evidence of Ms. Kitamura’s state-of-mind or intent to deceive the PTO, but eventually admit that they are offering her opinions as “circumstantial evidence” of intent. Plaintiffs argue that although expert evidence of intent is generally improper, this inferential expert evidence of intent is proper as a matter of law, because her opinions are only a “frame of reference.”

The Court should reject this argument for three reasons. First, there are several places in Ms. Hino’s report in which she opines directly as to the state of mind of Ms. Kitamura and Mr. Yasumi. Second, this Court and courts around the country exclude expert evidence from which state of mind or intent may be inferred. Third, the Court’s determination of Ms. Kitamura’s intent to deceive the PTO does not require, and will not be aided, by Ms. Hino’s speculative comparison to theoretical Japanese practitioners. The only question is what Ms. Kitamura

¹ Unless indicated otherwise, all citations herein to “Ex.” refer to the exhibits attached to the Declaration of Payson LeMeilleur, filed with Defendants’ Opening Brief.

subjectively intended with respect to the U.S. application — not what the hypothetical average or reasonable Japanese patent practitioner might have understood about the U.S. duty of disclosure.²

Plaintiffs next argue that Ms. Hino is needed because Japanese patent law is at issue in this case. That is not true. This inequitable conduct case does not turn on or involve a question of Japanese patent law. It turns on the state of mind or intent of Ms. Kitamura and her colleagues in the Shionogi patent department when they withheld highly material references from the PTO. Throughout their opposition brief, Plaintiffs incorrectly attempt to demonstrate a need for Ms. Hino's testimony by mischaracterizing the issue of intent — which is a *subjective* inquiry — as though it were an objective inquiry. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In any event, the certified translation of that memorandum and Mr. Yasumi's sworn deposition testimony speak for themselves, they need not and should not be re-interpreted by Ms. Hino.

Finally, Plaintiffs claim that the Court "needs" Ms. Hino because the alleged inequitable conduct happened in Japan, and because her narrative summary evidence is essential to the Court's understanding of the "dense, scientifically complex, Japanese language patent file

² Not only does Ms. Hino's testimony on the U.S. duty of disclosure fail to satisfy the requirements of Rule 702, Ms. Kitamura and others' awareness of the duty is not even in dispute. Indeed, Plaintiffs affirmatively represented to the Court that "Shionogi does not contend that its patent department employees were not apprised of the existence of a U.S. duty of disclosure," in seeking to prevent Defendants' requested discovery into the subject. *See* 08-md-1949, D.I. 168 at 3. The Court denied Defendants' requested discovery on the basis of that representation. *See* 08-md-1949, D.I. 169 at 2.

history.” Opp’n Br. at 23. Whether the conduct occurred in Japan, and whether U.S. and Japanese patent laws differ, is simply irrelevant to the question of whether Ms. Kitamura and her colleagues acted with the subjective intent to deceive the PTO. And even if certified translations of a single Japanese prosecution file were too much for the Court to handle (which they plainly are not), Ms. Hino’s proffered narrative is not a summary of what the documents say. Rather, it is a re-hash of the assumptions and inferences that Plaintiffs’ counsel argued in their recently-filed motion for summary judgment of no inequitable conduct. While Plaintiffs are entitled to maintain those arguments at trial, they are not entitled to present them as substantive expert opinion evidence. Thus, Defendants’ present motion to exclude should be granted as to all of Ms. Hino’s proposed expert testimony.

II. ARGUMENT

A. The Court Should Exclude Ms. Hino’s Expert Testimony Regarding The State Of Mind Or Intent Of Ms. Kitamura And Her Shionogi Patent Department Colleagues

1. Ms. Hino proposes to offer direct and inferential evidence of the state of mind or intent of Ms. Kitamura and her Shionogi patent department colleagues

Throughout her expert report, Ms. Hino offers multiple direct opinions as to the state of mind of Ms. Kitamura, which is a key fact issue, and that of Mr. Yasumi, which is not at issue. Ms. Hino bases all of these opinions solely on her review of documents selected by Plaintiffs’ counsel.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] By opining as to what Ms. Kitamura “recognized,” Ms. Hino opines as to Ms. Kitamura’s state of mind. *See Oxford Gene Tech. Ltd. v. Mergen Ltd.*, 345 F. Supp. 2d 431, 443 n.9 (D. Del. 2004).

Another such opinion concerns a potentially key issue to Defendants’ claim that Shionogi’s re-issue of its U.S. application was improper. The re-issue statute expressly limits the availability of re-issue to fix defective claims that came about as a result of “error” — not intentional decisions to draft claims covering prior art. Defendants contend that re-issue was improper because it was not by “error” that Shionogi broadened the inventor’s initial claims to cover the known-but-undisclosed Bayer and Sandoz references. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

In another section of her report, Ms. Hino opines that it was very difficult for patent practitioners in Japan to “understand” and “appreciate” the duty to disclose in the early 1990s, because there was not a lot of opportunity for them to learn about it. Ex. 9 (Hino Report) ¶¶ 28-47. It is unclear whether Ms. Hino is referring to an unspecified group of actual patent practitioners, or is intending to opine as to what the hypothetical “average” or “reasonable” Japanese patent practitioner knew about the duty to disclose. Whether speaking for all Japanese patent practitioners or the hypothetical “reasonable” practitioner, however, it is clear that the basis for her opinions about the state of such practitioners’ “understanding” is no more than her recollection of interactions with unspecified clients at the time (when she began her own legal career, having become a Japanese patent attorney (“benrishi”) in 1990) and her social circle of college friends, some unspecified number of whom went to work in patent departments of various Japanese companies. Ex. 8 (Hino Dep.) at 198:3-199:12, 200:7-22.

2. The Court should reject Ms. Hino’s proposed expert evidence of state of mind or intent, as a matter of law, even if characterized as “circumstantial”

Plaintiffs do not dispute that expert evidence of state of mind or intent is improper as a matter of law. Accordingly, Plaintiffs simply deny the existence of Ms. Hino’s direct opinions as to state of mind, which they in part attempt to bury in the supposed “summary evidence” section of her report. Ex. 9 (Hino Report) ¶¶ 59-98. The text of her report discussed above speaks for itself. Ms. Hino seeks to opine as to what Ms. Kitamura “recognized” and “intended” on at least two potentially key issues in Defendants’ inequitable conduct and improper re-issue defenses.

Plaintiffs argue that although such direct expert evidence of intent is improper, “circumstantial” expert evidence from which intent can be “inferred” is admissible because it is merely a “frame of reference.” Opp’n Br. at 13. In support of this theory, Plaintiffs rely upon the *Oxford* case. That case, however, not only fails to support Plaintiffs’ position, but expressly

rejects it. This Court held that experts are not permitted to testify regarding “intent, motive, or state of mind, *or evidence by which such state of mind may be inferred*,” as a matter of law. *Oxford*, 345 F. Supp. 2d at 443 (emphasis added). This Court and courts around the country continue to reject such inferential expert evidence of intent. *See, e.g., AstraZeneca LP v. TAP Pharm. Prods., Inc.*, 444 F. Supp. 2d 278, 293 (D. Del. 2006) (expert not permitted to present “evidence by which such state of mind may be inferred”); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) (“Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony.”).

Plaintiffs’ specious legal argument is based on a selective reading of the *Oxford* case. As an initial matter, Plaintiffs simply ignore the *Oxford* court’s express rejection of proffered expert evidence of defendant’s state of mind, as well as “evidence by which such state of mind may be inferred.” *Oxford*, 345 F. Supp. 2d at 443. Plaintiffs instead rely on the portion of that decision in which the court allowed expert evidence of objectively reasonable corporate conduct with respect to willfulness, as a “frame of reference” to allow the jury to perform the necessary comparison of defendant’s conduct “against an objective standard of reasonable commercial behavior under the same circumstances.” *Id.* (internal citation omitted). In the case at bar, however, there is no issue of *objectively* reasonable conduct that requires or permits expert testimony as a “frame of reference” to facilitate a comparison. The comparison between the actual conduct in question and an objective standard of reasonable conduct that was present in *Oxford* (a willful infringement case) forms no part of the law of inequitable conduct. Here, the Court is only confronted with the subjective intent or state of mind of Ms. Kitamura and her Shionogi colleagues who withheld highly material references from the PTO.

Plaintiffs' other authority is likewise unavailing. *United States v. Mathis*, 264 F.3d 321 (3d Cir. 2001), for example, is a criminal bank robbery case in which there is no issue of intent whatsoever. The trial court in *Mathis* excluded testimony from an acknowledged expert in the field of human perception and memory, which challenged the reliability of an eye-witness' identification of the defendant. *Id.* at 333-42. The Third Circuit held that the trial court had erred in excluding the testimony, but affirmed because it was harmless error in light of other evidence of guilt. *Id.* at 342-44. *Mathis* is not instructive on any issue presented in this case.

Finally, Plaintiffs also attempt to argue that Ms. Hino's testimony must be admitted because the court in *Tap Pharm. Prods., Inc. v. Owl Pharms., LLC*, No. 1:99 CV 2715, 2003 WL 25695241, at *1 (N.D. Ohio Feb. 18, 2003), while excluding a proffered "patent law expert's" testimony regarding intent (as Defendants' seek here), permitted him to provide the court with "background information to put relevant PTO practices and procedures in context." It is important to note here that Plaintiffs repeatedly disavow that Ms. Hino is being offered as an expert on U.S. law or PTO practices and procedures, even though she devotes five paragraphs of her report to an explanation of U.S. patent law. *Compare* Opp'n Br. at 2 ("Defendants wrongly assert that Ms. Hino offers opinions on U.S. law.") *with* Ex. 9 (Hino Report) at ¶¶ 35-39 (opining as to the governing U.S. law before and after conduct at issue). But even if she were offered as a U.S. patent law expert, the bounds of her testimony would be limited by this Court's guidelines and practice with respect to such experts. *See* Opening Br. at 11 (citing authority). In any event, *Tap* does not authorize any sort of "background" testimony relating to intent.

Whether expressed as direct opinions or suggested inferences, expert evidence of a person's state of mind does not "fit," because it does not assist the trier of fact in assessing what is the most reasonable inference to be drawn from the documentary and testimonial evidence.

Moreover, it is completely inappropriate here in view of the direct testimony given by Ms. Kitamura and her colleagues about their actual understanding of the U.S. duty of disclosure, as well as the contemporaneous documentary evidence further establishing that understanding. Thus, Plaintiffs' blatant attempt to impeach their own testimonial and documentary evidence through the guise of "expert" testimony should be flatly rejected.

Even if experts were allowed to testify regarding circumstantial evidence of intent, Ms. Hino's testimony should be excluded because it lacks a reliable or even a reasonable basis. She relies primarily on her own interpretation of the Shionogi documents selected by Plaintiffs' counsel, anecdotal evidence from old college friends, and promotional brochures (not curricula) for some U.S. law seminars available in Japan. She never attended these seminars and does not know whether Ms. Kitamura or anyone else at Shionogi did so. *See* Opening Br. at 7; *see also Rezulin*, 309 F. Supp. 2d at 546-47 (rejecting inferences from review of documents as basis for expert testimony).

In this case, however, the Court need not wonder about the reliability of Ms. Hino's methods. There is concrete evidence that they are unreliable, and Ms. Hino has admitted as much. [REDACTED]

[REDACTED] Ms. Hino admitted that her opinion was not the truth, and was in fact the opposite of the truth. Ex. 8 (Hino Dep.) at 44:15-47:9, 66:15-23. Additionally, Ms. Hino was proven wrong about her blanket assertion that the Bayer reference had never formed the basis for a rejection of the subject matter of the patent-in-suit. Opening Br. at 14. Moreover, throughout her deposition, Ms. Hino admitted that

C. The Court Should Exclude Ms. Hino's Alleged "Summary" Evidence

Plaintiffs suggest that there is no need to scrutinize the last section of Ms. Hino's report because it is merely "summary evidence" under Fed. R. Evid. 1006 and necessary for the Court to be able to handle the "dense, scientifically complex, Japanese language patent file." Opp'n Br. at 23. In fact, the certified translation of this patent prosecution file is no more difficult for the Court to understand than any other patent application file. Moreover, many of the documents Ms. Hino purports to summarize are correspondence to and from the U.S. and European patent offices and, thus, are in English, not Japanese. The Court does not require any "expert" assistance in this regard, and should exclude such testimony for this reason alone. *See Bausch & Lomb, Inc. v. Alcon Labs., Inc.*, 79 F. Supp. 2d 252, 256 (W.D.N.Y. 2000) (excluding expert testimony that merely outlines the prosecution history because such evidence can be presented through documents and fact witness testimony); *Rezulin*, 309 F. Supp. 2d at 551 (excluding expert testimony consisting of a narrative of factual events because "[s]uch material, to the extent it is admissible, is properly presented through percipient witnesses and documentary evidence"); *Highland Capital Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 468-69 (S.D.N.Y. 2005) ("To the extent that [an expert] is simply rehashing otherwise admissible evidence about which he has no personal knowledge, such evidence-taken on its own-is inadmissible.").

In actuality, Plaintiffs seek to offer Ms. Hino's "summary" opinions as a pretext to introduce more improper testimony. Rather than summarizing, Ms. Hino uses a "prism of generalizations" to interpret, comment upon, evaluate, assume and infer from the documents in the file. Opp'n Br. at 24. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Thus, the “summary” section of Ms. Hino’s report is not mere summary. Rather, under the guise of summary, Ms. Hino seeks to proffer her personal inferences made from a simple review of documents and tries to recast the record to accord with Plaintiffs’ theory of the case. While Plaintiffs are entitled to argue in favor of those inferences at trial, nothing — including mischaracterizing them as benign “summary” testimony — justifies having such inferences introduced as substantive expert evidence.

III. CONCLUSION

Based on the foregoing, Defendants respectfully request the Court exclude the expert report and testimony of Mami Hino pursuant to *Daubert* and Rule 702.

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CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on October 30, 2009, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

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